▲ AO 120 (Rev. 3/04)

TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office

REPORT ON THE FILING OR DETERMINATION OF AN

P.O. Box 1450 Alexandria, VA 22313-1450			ACTION REGARDING A PATENT OR TRADEMARK		
_	ce with 35 U.S.C. § 290 and/or 15		116 you are hereby advise	ed that a court acti	ion has been ☐ Trademarks:
DOCKET NO.	DATE FILED	U.S. DIS	TRICT COURT		
07cv204	4 <u>/1</u> 7/07	l		CT OF DELAWA	RE
PLAINTIFF MedPointe Healthcare Inc.			DEFENDANT Apotex Inc.; Apotex Cor	p.	:
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF P	ATENT OR TRA	DEMARK
1 5,164,194	11/17/92		As	sta Pharma AG	
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PATENT OR	DATE OF PATENT	dment	Answer C	ross Bill	Other Pleading
TRADEMARK NO.	OR TRADEMARK		HOLDER OF P	ATENT OR TRA	DEMARK
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In the abo	ve—entitled case, the following de	cision has	been rendered or judgeme	ent issued:	
DECISION/JUDGEMENT COMPACTOR CONSCIONA	4-2108 per fina				nut · Order.
See Atta	Ug				
CLERK		PEPUTY	CLERK		DATE 44.2/19Q
PETER T. DALLEO,			Daw		April 18, 2007

FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC.,)))
Plaintiff,) Civil Action No. 07-204-SLR
)
v.)
APOTEX INC. and APOTEX CORP.,)))
Defendants.	j
)

FINDINGS OF FACT AND CONSENT JUDGMENT AND ORDER

The Court, upon the consent and request of Plaintiff, Meda Pharmaceuticals Inc., formerly known as MedPointe Healthcare Inc. ("Meda"), and Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), hereby makes the following Findings of Fact and issues the following Consent Judgment and Order:

FINDINGS OF FACT

- i. This Court has subject matter jurisdiction over this patent infringement action (the "Action") and personal jurisdiction over all of the parties to the Action. Venue is proper in this Court as to all parties to the Action.
- In this Action, Meda has charged Apotex with infringement of United States Patent No. 5,164,194 ("the '194 Patent") in connection with Apotex's submission of Abbreviated New Drug Application ("ANDA") 78-621 directed to a generic azelastine hydrochloride ophthalmic solution to the U.S. Food and Drug Administration ("FDA").

- 3. In response to Meda's charge of patent infringement, Apotex has alleged certain defenses and counterclaims, including that the '194 Patent is invalid, unenforceable and not infringed by the generic azelastine hydrochloride ophthalmic solution defined by ANDA 78-621.
- 4. The claims, defenses and counterclaims in this action were scheduled for trial beginning on February 23, 2009.
- 5. Apotex has not rebutted the statutory presumption that the '194 Patent is valid and enforceable in this Action. This admission, however, is without prejudice to Apotex's allegations that the asserted claims of the '194 patent are invalid and unenforceable.
- 6. Apotex admits that the submission of ANDA 78-621 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of a generic azelastine hydrochloride ophthalmic solution, the use of which is claimed in the '194 Patent, within the United States before the expiration of the '194 Patent is an act of patent infringement. This admission, however, is without prejudice to Apotex's allegations that the asserted claims of the '194 patent are invalid and unenforceable.
- 7. Apotex has agreed that each of the defenses and counterclaims set forth in Defendants Apotex Inc.'s And Apotex Corp.'s Answer, Defenses and Counterclaims in this Action, including the allegations and averments contained therein, should be dismissed, without prejudice.

CONSENT JUDGMENT AND ORDER

Accordingly, pursuant to the above Findings of Fact, and upon the consent and request of Meda and Apotex, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

- 1. The filing of ANDA 78-621 was a technical act of infringement of the '194 Patent under 35 U.S.C. § 271(e)(2)(A).
- Apotex's defenses and counterclaims with respect to the '194 Patent are hereby dismissed, without prejudice.
- 3. Apotex, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic azelastine ophthalmic solution defined by ANDA 78-621 during the life of the '194 Patent, including any extensions and pediatric exclusivity, absent authorization by Meda, unless all of the claims of the '194 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken.
- 4. Meda and Apotex each expressly waives any right to appeal or otherwise move for relief from these Findings of Fact and Consent Judgment and Order.
- This Court retains jurisdiction over Meda and Apotex for purposes of enforcing these Findings of Fact and Consent Judgment and Order.
- 6. These Findings of Fact and Consent Judgment and Order shall finally resolve this Action between Meda and Apotex. Each party shall bear its own fees and costs in connection with this action, including attorney fees.
 - 7. The Clerk of the Court is directed to enter this final judgment forthwith.

SO ORDERED:

HONORABLE SUE L. ROBINSON UNITED STATES DISTRICT JUDGE